

Remarks

Claims 1-58 are pending. Claims 1-58 are rejected.

Objections to the Claims

The Examiner has objected the claims 6-7, 17-18, and 28-29 under 37 CFR 1.75(c) as allegedly being in improper form because a multiple dependent claim cannot depend upon another multiple dependent claim.

Claim 6 depends on any of claims 1-5 and is a proper multiple dependent claim (See MPEP § 608(n), I, A: Acceptable multiple dependent claim wording).

Claim 7 depends on claim 6 only and is a proper dependent claim (See MPEP § 608(i), 37 CFR 1.75(c)).

Claim 17 depends on any of claims 12-16 and is a proper multiple dependent claim (See MPEP § 608(n), I, A: Acceptable multiple dependent claim wording).

Claim 18 depends on claim 17 only and is a proper dependent claim (See MPEP § 608(i), 37 CFR 1.75(c)).

Claim 28 depends on any of claims 23-27 and is a proper multiple dependent claim (See MPEP § 608(n), I, A: Acceptable multiple dependent claim wording).

Claim 29 depends on claim 28 only and is a proper dependent claim (See MPEP § 608(i), 37 CFR 1.75(c)).

In sum, Applicants believe that these claims are in are proper form.

Rejections under 35 U.S.C. § 103(a)

Claims 1-58 are rejected under 35 U.S.C. §103(a) as being obvious over Pacetti (WO 03/022323) in view of Roby (WO 98/32398).

Claim 1 defines a method for forming a poly(ester amide) (PEA) coating with enhanced mechanical and release rate properties. The method includes (a) applying to an implantable device a solution or suspension of a composition comprising PEA and a low surface energy, surface blooming polymer, and (b) forming a coating on the implantable device comprising PEA and the low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer includes a PEA miscible block or PEA miscible backbone. As described on Page 7, lines 10-22 of the instant application, the method will cause the surface of a coating thus formed to be enriched with the hydrophobic blooming component in the blooming polymer. This would reduce or prevent the interaction between the PEA polymer and the catheter balloon, thereby reducing potential mechanical failures of a PEA coating on an implantable device. Additionally, the hydrophobic, blooming component of the polymer would create a hydrophobic barrier at the coating surface, thereby retarding drug release from the PEA matrix. As a result, thinner coatings can be used to obtain the same release rate control of a thicker coating of PEA polymer without the surface blooming polymers. Further, the hydrophobic barrier would further reduce the interaction between water and the PEA matrix so as to reduce the degradation rate of the PEA polymer.

Pacetti describes a coating for reducing the release rate of a therapeutic agent from the coating. The coating includes a polymer capable of maintaining its crystalline lattice structure

while the therapeutic agent is released from the coating. As the Examiner correctly notes, Pacetti does not describe a coating that includes a PEA.

Further, Pacetti fails to teach or suggest a method of forming a coating for an implantable device using a composition comprises a low surface energy, surface blooming polymer that has a PEA miscible block or a PEA miscible backbone as required by claim 1.

Roby discloses the preparation of a poly(ester amide) (PEA) polymer that can be used for fabrication of surgical devices. However, there is no teaching in Roby of a method of forming a coating comprising applying to an implantable device a composition that comprises a PEA polymer and a low surface energy, surface blooming polymer that includes a PEA miscible block or PEA miscible backbone.

In sum, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 1 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 2-7 and 53 depend from claim 1 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 8 defines a method of forming a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 8 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 9-11 and 54 depend from claim 8 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 12 defines coating composition for coating an implantable device. The composition comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 12 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 13-18 and 55 depend from claim 12 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 19 defines a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises a PEA miscible block or PEA miscible backbone. As the discussion of claim 8 shows, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 19 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 20-22 and 56 depend from claim 19 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 23 defines an implantable device comprising a coating which comprises a poly(ester amide) (PEA) and a low surface energy, surface blooming polymer. The low surface energy, surface blooming polymer comprises a PEA miscible block or PEA miscible backbone. As discussed above, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 23 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 24-29, 34-38, 41, 42, 45-49, 51 and

57 depend from claim 23 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claim 30 defines an implantable device comprising a coating having a PEA polymer and at least one low surface energy polymer additive. The at least one low surface energy polymer additive comprises **a PEA miscible block or PEA miscible backbone**. As discussed above, Pacetti and Roby, individually or combined, fail to teach or suggest these elements. Therefore, claim 30 is patentably allowable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a). Claims 31-33, 39, 40, 43, 44, 50, 52 and 58 depend from claim 30 and are patentable over Pacetti and Roby, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

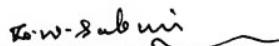
The undersigned authorizes the Examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

Withdrawal of the rejection and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0313.

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Respectfully submitted,

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